

PTO-1390 (Rev. 2-2005)
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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER
478.1076

U.S. APPLICATION NOW IN A STREET OF ASSIGNED STREET

INTERNATIONAL APPLICATION NO. PCT/GB2004/003935

INTERNATIONAL FILING DATE
15 September 2004

PRIORITY DATE CLAIMED

15 September 2003

TITLE OF INVENTION

PHARMACEUTICAL COMPOSITIONS FOR TREATING PREMATURE EJACULATION BY PULMONARY INHALATION APPLICANT(S) FOR DO/EO/US David MORTON; John STANIFORTH; Mike TOBYN; Stephen EASON; Quentin HARMER and David GANDERTON Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371. This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371. This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items 3. (5), (6), (9) and (21) indicated below. The US has been elected (Article 31). A copy of the International Application as filed (35 U.S.C. 371(c)(2)) is attached hereto (required only if not communicated by the International Bureau). has been communicated by the International Bureau. is not required, as the application was filed in the United States Receiving Office (RO/US). An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). is attached hereto. has been previously submitted under 35 U.S.C. 154(d)(4). 7. Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are attached hereto (required only if not communicated by the International Bureau). have been communicated by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. have not been made and will not be made. An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). 10. 🔲 An English language translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Items 11 to 20 below concern document(s) or information included: 11. An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. A preliminary amendment. 14. An Application Datasheet under 37 CFR 1.76. 15. A substitute specification. 16. A power of attorney and/or change of address letter. 17. A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825. 18. A second copy of the published international application under 35 U.S.C. 154(d)(4). 19. A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. Other items or information: Letter re: Priority; Form PTO-1449 with copies of references cited therein; Appendix A; unexecuted Declaration and Power of Attorney; Certificate of Mailing By Express Mail; return receipt postcard.

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing the burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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U.S. APPO CAS	To be	Assigne	ểρ \$77 C:F7R. 1.5	internation		PPLICATION 04/003935	NO.			Y'S DOCKET NO. 7 8.1076
The	e following fees have been submitted								TIONS	PTO USE ONLY
21.	Basic nat	tional fee				\$300		\$ 300.00		
22. Examination fee										
If International preliminary examination report prepared by USPTO ands all claims satisfy provisions of PCT Article 333(1)-(4) \$100 All other situations \$200								\$ 200.00		
23. Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority								\$ 400.00		
TOTAL OF 21, 22 and 23 =								\$ 900.00		
Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.										
Total Sheets	Extra Sheets		Number of each additional 50 or fraction thereof (round up to a whole number)			RATE]		
57 - 100 =	/50 =					x \$250	=	\$		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e))+								\$		
CLAIMS	<u>`</u>	NUME	BER FILED	NUMBER EXTRA		RATE				
Total Claims			35 - 20 =	15	×	\$50	=	\$750.00		
Independent C			1 - 3 =	0	×	\$200	=	\$		ļ
MULTIPLE DEPENDENT CLAIM(S) (if applicable) + \$360 +								\$		
TOTAL OF ABOVE CALCULATIONS =								\$ 1650.00		
Applicant claims small entity status. See 37 C.F.R. 1.27. Fees above are reduced by ½.								\$		
SUBTOTAL =								\$		
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).								\$		
TOTAL NATIONAL FEE =								\$ 1650.00		
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property +								\$		
TOTAL FEES ENCLOSED =								\$ 1650.00		
									be	\$
								Amount to charged:	be	\$
a. 🔀 A check in the amount of \$1650.00 to cover the above fees is enclosed.										
b. Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed.										
c. The Commissioner is hereby authorized to charge any additional fees which may be required, or caedit any overpayment to Deposit Account No. 50-0552. A duplicate copy of this sheet is enclosed.										
d. Fees are to be charged to a credit card. WARNING: Information on this form may become pulylic. Credit card information										
should not be included on this form. Provide credit card information and authorization on FTO-2038. NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or										
(b)) must be filed and granted to restore the application to pending status. SEND ALL CORRESPONDENCE TO:										
Davidson, Davidson & Kappel, LLC SIGNATURE								/		
485 Seventh A New York, NY		Cary S. Kappel								
(212)-736-1940 NAME										
Dated: March 8, 2006 36,561 REGISTRATION NUMBER								ж		

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Re.:

Docket No.: 478.1076

Applicant(s): David MORTON, et al.

Serial No.: To be Assigned

Invention: PHARMACEUTICAL COMPOSITIONS FOR TREATING PREMATURE EJACULATION BY

PULMONARY INHALATION

Filing Date: Herewith

Enclosed Are:

- Certificate of Mailing by Express Mail (1 page)
- Transmittal Letter to the U.S. Designated/Elected Office Concerning a Filing Under 35 U.S.C. 371 (2 pages);
- Application Data Sheet (3 pages);
- Copy of Unexecuted Declaration and Power of Attorney Form (2 pages);
- Letter re: Priority (1 page);
- Preliminary Amendment (8 pages);
- Copy of Int. Patent Application PCT/GB2004/003935 (55 pages);
- One (1) Sheet of Drawings;
- Information Disclosure Statement (2 pages);
- Form PTO-1449 (1 page) with references citedo therein;
- Appendix A (5 pages); and
- Check in the amount of \$ 1650.00) TEXTS POSTC AT &

This collection of information is required by 37 CFR 1.10. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.8 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450.DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.